UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CENTER FOR FOOD SAFETY, BREAST CANCER PREVENTION PARTNERS, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, ENVIRONMENTAL DEFENSE FUND, and ENVIRONMENTAL WORKING GROUP,	17-CV-3833 (VSB)
Plaintiffs,	**OPINION & ORDER**
- against -	
TOM PRICE, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; SCOTT GOTTLIEB, COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION; and UNITED STATES FOOD AND DRUG ADMINISTRATION,	
Defendants.	

Appearances:

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VERNON S. BRODERICK, United States District Judge:

Plaintiffs Center for Food Safety ("CFS"), Breast Cancer Prevention Partners, Center for Science in the Public Interest, Environmental Defense Fund ("EDF"), and Environmental Working Group filed this action seeking declaratory and injunctive relief with respect to a final rule promulgated by the United States Food and Drug Administration ("FDA") entitled "Substances Generally Recognized as Safe," 81 Fed. Reg. 54,960 (Aug. 17, 2016) (the "GRAS Rule"). Defendants Thomas Price, Secretary of Health and Human Services; Scott Gottlieb, Commissioner of Food and Drugs; and FDA (the "Government") moved to dismiss the action for lack of standing pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. Because I find that Plaintiffs CFS and EDF have standing to pursue their claims based on harm to their members, the Government's motion is DENIED as to those Plaintiffs. The Government's motion is GRANTED as to Plaintiffs Breast Cancer Prevention Partners, Center for Science in the Public Interest, and Environmental Working Group.

I. Background[1]

The Food, Drug, and Cosmetic Act (the "FDCA") requires FDA to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled." (Compl. ¶ 33 (quoting 21 U.S.C. § 393(b)).)[2] In 1958, Congress enacted the Food Additives Amendment to the FDCA (the "1958 Amendment") in response to concern among the public, lawmakers, and leading scientists that the food industry's increasing use of untested chemical additives in food—as well as the lack of information about the possible risks posed by such chemicals—posed a

[1] The following factual summary is drawn from the allegations in the complaint, which I accept as true for the purposes of this motion pursuant to Rule 12(b)(1). *See Raila v. United States*, 355 F.3d 118, 119 (2d Cir. 2004). My references to these allegations should not be construed as a finding as to their veracity, and I make no such findings.

[2] "Compl." refers to the Complaint for Declaratory and Injunctive Relief ("Complaint"), filed on May 22, 2017. (Doc. 1.)

health risk to consumers. (*Id.* ¶ 34.) The purpose of the 1958 Amendment is "to prohibit the use in food of additives which have not been adequately tested to establish their safety." (*Id.* ¶ 35 (quoting Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784).)

To accomplish this purpose, the 1958 Amendment mandates that any "food additive" must go through an approval process. (*Id.* ¶ 36.) Under this process, "the burden is on the manufacturer to prove the safety of the use of the substance," and "FDA must review and approve the proposed use before the additive can be used in food." (*Id.*) FDA considers, among other things, "the probable consumption of the additive and of any substance formed in or on food because of the use of the additive," and "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet." (*Id.* ¶ 41 (quoting 21 U.S.C. § 348(c)(5).)

The 1958 Amendment also provides a role for the public in the approval of food additives. (*Id.* ¶ 43.) Specifically, it requires that FDA publish notice of a proposed food additive regulation and the agency's final decision on the underlying petition. (*Id.*) Any person adversely affected by FDA's final decision may file objections and request a public hearing, and the final decision is also subject to judicial review. (*Id.*); *see also* 21 U.S.C. § 348(f)–(g).

The 1958 Amendment defines a "food additive" to include "any chemical substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." (Compl. ¶ 45); *see also* 21 U.S.C. § 321(s). This definition exempts a category of substances that are:

> generally recognized, among experts qualified by scientific training and experience to evaluate [their] safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of [their] intended use.

(Compl. ¶ 45.) Because substances generally recognized as safe ("GRAS") are not considered "food additives," manufacturers can bypass the food additive approval process, including public participation and the option of judicial review. (*Id.* ¶¶ 43, 47.)

Prior to the proposed GRAS Rule, manufacturers could file a petition asking FDA to affirm the GRAS status of a particular use of a substance, thereby confirming that the substance was not a food additive under the FDCA. (*Id.* ¶ 49.) In so doing, manufacturers were required to provide FDA with information supporting the general scientific agreement that the proposed use was safe. (*Id.*) Within thirty days of receiving a petition, FDA was required to publish a notice of filing in the Federal Register and allow a sixty-day comment period. (*Id.*) After considering a manufacturer's petition, scientific data, and any comments, FDA could either publish an order that added the substance to the list of affirmed GRAS substances or publish a ruling that the substance was not GRAS and therefore a food additive. (*Id.*) FDA's explanation was required to be published in the Federal Register. (*Id.*)

"In April 1997, FDA proposed the GRAS Rule, weakening the prior regulatory scheme by repealing manufacturers' option of filing a GRAS affirmation petition and seeking FDA approval of their GRAS determinations." (*Id.* ¶ 50.) "Under the proposed GRAS Rule, manufacturers independently made GRAS determinations, and FDA did not review, affirm, or reject those determinations." (*Id.*) Manufacturers were given the option of notifying FDA that they had concluded that a use of a chemical substance is GRAS. (*Id.*) "With the proposed GRAS Rule, FDA also weakened the substantive criteria by which a manufacturer determines whether the use of one of its chemical substances is GRAS." (*Id.*); *see also* Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (Apr. 17, 1997) (proposed rule).

FDA operated under this proposed GRAS Rule for nineteen years before publishing the

final GRAS Rule on August 17, 2016. (Compl. ¶¶ 51, 53.) The GRAS Rule codified FDA's practice of allowing "self-certified" GRAS chemical substances to be added to food without FDA review, approval, oversight, or knowledge, and without participation from the public. (*Id.* ¶ 53); *see also* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960 (Aug. 17, 2016). Therefore, although the final GRAS Rule was promulgated recently, it codifies a practice that has been in effect for nearly 20 years. (Compl. ¶ 53.)

The GRAS Rule allows manufacturers and other private entities to determine the safety of their products without agency oversight, public participation, or judicial review. (*See id.* ¶¶ 47, 50–53.) Although much of the GRAS Rule describes a notification process that manufacturers could use to provide notice to FDA of self-certified GRAS determinations, the Rule does not require notice. (*See id.* ¶ 98.) Instead, the GRAS Rule adopts a voluntary approach for the manufacturer, under which notifying FDA about a GRAS determination is entirely optional. (*Id.* ¶¶ 55–57); *see also* 81 Fed. Reg. at 54,960, 54,970, 54,986. Nor does the GRAS Rule require manufacturers to keep records documenting or explaining the basis of GRAS determinations. (Compl. ¶¶ 6, 100.) Since GRAS determinations and the use of GRAS substances in food are not required to be disclosed, they remain entirely secret from FDA and the public. (*Id.* ¶¶ 6, 88–89.)

In addition, the GRAS Rule lacks safeguards against potential conflicts of interest. (*Id.* ¶ 69); *see also* 81 Fed. Reg. at 55,026. As a result, it is common for safety determinations to be made by panels of experts who are linked to the manufacturer of the substance at issue. (Compl. ¶¶ 70, 107.) Finally, GRAS determinations are insulated from judicial review because there is no final agency action to challenge. (*Id.* ¶¶ 47, 93.)

On May 22, 2017, Plaintiffs—a group of nonprofit advocacy organizations—filed this

action seeking a declaratory judgment that the GRAS Rule (1) violates fundamental principles of separation of powers, (2) exceeds FDA's statutory authority, (3) does not accord with the law, (4) is arbitrary and capricious, and (5) is an abuse of discretion. (*Id.* ¶¶ 14, 19–28.) Plaintiffs also seek equitable relief vacating the GRAS Rule and directing FDA to reissue a rule that is in accordance with the FDCA. (*Id.* ¶ 14.) Plaintiffs allege that the GRAS Rule allows manufacturers to decide whether their own products are safe, which in turn constitutes an unlawful abdication of FDA's duty to ensure food safety. (*Id.* ¶¶ 94–104, 129–32.) In addition, Plaintiffs allege that, even if it were permissible for FDA to delegate food safety determinations to manufacturers, the GRAS Rule's substantive criteria for what constitutes "general recognition" of "safety" in the context of substances added to food are inconsistent with the FDCA and cannot stand. (*Id.* ¶¶ 105–11, 129–32.)

II. Legal Standards

A. *Rule 12(b)(1)*

A court may dismiss a case for lack of subject matter jurisdiction under Rule 12(b)(1) when the court "lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). It is the plaintiff's burden to prove, by a preponderance of the evidence, that subject matter jurisdiction exists. *Id.* In considering a motion to dismiss under Rule 12(b)(1), a court must accept as true all well-pleaded facts alleged in the complaint and must draw all reasonable inferences in the plaintiff's favor. *See Raila*, 355 F.3d at 119. "Dismissal is inappropriate unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him or her to relief." *Id.*

B. *Article III Standing*

The Constitution limits the judicial power of the federal courts to deciding cases or

controversies. U.S. Const. art. III § 2, cl.1. "The doctrine of standing is derived directly from this constitutional provision." *In re Bennett Funding Grp., Inc.*, 336 F.3d 94, 99 (2d Cir. 2003) (internal quotation marks omitted). "To satisfy the 'irreducible constitutional minimum of standing,' a plaintiff 'must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *John v. Whole Foods Mkt. Grp., Inc.*, 858 F.3d 732, 736 (2d Cir. 2017) (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016)). "Each element of standing 'must be supported with the manner and degree of evidence required at the successive stages of the litigation,' and at the pleading stage, 'general factual allegations of injury resulting from the defendant's conduct may suffice.'" *Id.* (quoting *Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 561 (1992)). When a defendant mounts a "facial" challenge to a plaintiff's allegations of standing, as here, the plaintiff "bears no evidentiary burden at the pleading stage." *Id.* Thus, the task of the court is to determine whether the complaint "alleges facts that affirmatively and plausibly suggest that the plaintiff has standing to sue." *Id.* (quoting *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 56 (2d Cir. 2016)).

"An organization can have standing to sue in one of two ways." *N.Y. Civil Liberties Union v. N.Y. Transit Auth.*, 684 F.3d 286, 294 (2d Cir. 2012). First, under "associational" or "representational" standing, an organization "may sue on behalf of its members, in which case it must show, *inter alia*, that some particular member of the organization would have had standing to bring the suit individually." *Id.* Second, under "organizational" standing, "an organization can 'have standing in its own right to seek judicial relief from injury to itself and to vindicate whatever rights and immunities the association itself may enjoy.'" *Id.* (quoting *Warth v. Seldin*, 422 U.S. 490, 511 (1975)). To qualify, the organization itself "must meet the same standing test

that applies to individuals." *Id.* (internal quotation marks omitted).

III. Discussion

A. *Injury-in-Fact*

To establish a cognizable injury-in-fact, a plaintiff must show that it has suffered "an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (citations and internal quotation marks omitted). Plaintiffs allege three types of harm in the Complaint: (1) harm from diversion of resources, (2) informational harm, and (3) harm to members. (*See* Pls.' Opp. 2.)[3] I agree with the Government that Plaintiffs fail to plausibly allege harm from diversion of resources or informational harm. However, I find that Plaintiffs CFS and EDF plausibly allege harm to their members at this stage of the proceedings; therefore, CFS and EDF satisfy the injury-in-fact requirement of standing.

1. Harm from Diversion of Resources

"[T]here can be no question that [an] organization has suffered injury in fact" when it suffers "injury to the organization's activities—with the consequent drain on the organization's resources." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). In arguing that Plaintiffs have standing because the GRAS Rule impairs their organizations' missions and activities, Plaintiffs rely on *Havens* and its progeny. (*See* Pls.' Opp. 15–16.) In *Havens*, Housing Opportunities Made Equal ("HOME"), a nonprofit corporation, brought suit alleging that the defendants attempted to steer members of racial and ethnic groups toward buildings occupied primarily by members of the same groups and away from buildings occupied primarily by members of other groups in violation of the Fair Housing Act of 1968. *See Havens*, 455 U.S.

[3] "Pls.' Opp." refers to Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss. (Doc. 35.)

at 366–67. HOME's mission was to increase equal opportunity in housing through, among other ways, operating a housing counseling service and investigating complaints concerning housing discrimination. *See id.* HOME argued that it had standing because these activities were frustrated by the defendants' racial steering practices. *See id.* at 368–69. The Court held that the plaintiff would suffer an injury-in-fact if the defendants' conduct "perceptibly impaired" its ability to provide counseling and referring services to its members, reasoning that "[s]uch concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests." *Id.* at 379.

Following the Supreme Court's decision in *Havens*, courts in this Circuit have held that an organization has standing where the defendant's conduct interferes with or burdens the organization's ability to carry out its usual activities. *See, e.g.*, *Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay*, 868 F.3d 104, 110 (2d Cir. 2017) ("[I]f the Ordinance achieves one of its principal objectives—disbursement of day laborers—[the organization] will inevitably face increased difficulty in meeting with and organizing those laborers."); *N.Y. Civil Liberties Union*, 684 F.3d at 295 (entity had organizational standing because its ability to represent its clients in administrative hearings was "impeded" by the defendant's policy barring public access to such hearings); *Olsen v. Stark Homes*, 759 F.3d 140, 158 (entity had organizational standing due to its diversion of resources from its housing advocacy and counseling services in order to investigate alleged discriminatory practices). The Second Circuit has "repeatedly held that only a perceptible impairment of an organization's activities is necessary for there to be an injury in fact." *Centro*, 868 F.3d at 110 (internal quotation marks omitted) (collecting cases); *see also Nnebe v. Daus*, 644 F.3d 147, 156–57 (2d Cir. 2011)

(concluding that impairment can be shown with "scant" evidence that a "perceptible opportunity cost" has been expended). This injury to an organization is comprised of two components—the "injury to the organization's activities" and the "drain" on its resources. *Havens*, 455 U.S. at 379.

Here, Plaintiffs fail to plausibly allege "diversion of resources" standing based on *Havens* and its progeny. The organizations in the cases cited above were all driven to divert resources in order to avert or to remedy some harm caused by a defendant's actions or policies. *See, e.g.*, *Nnebe*, 644 F.3d at 157 (taxi-drivers' union had organizational standing to challenge a license-suspension policy because it needed to allocate resources to assist members with suspension proceedings). Here, by contrast, Plaintiffs fail to allege how the GRAS Rule causes Plaintiffs divert resources from "other current activities." *Centro*, 868 F.3d at 110. Nor do Plaintiffs sufficiently allege that their organizations were compelled to expend resources to counteract or remedy some harm imposed by Defendants' conduct. *See Ragin v. Harry Macklowe Real Estate Co.*, 6 F.3d 898, 905 (2d Cir. 1993) (finding that housing entity's performance of "regular tasks" was perceptibly impaired by need to devote resources to identify and counteract defendants' racially discriminatory advertising).

Plaintiffs argue that their organizational missions "include[] protecting people from eating unsafe food and ensuring food safety and the integrity of the food system" and that the GRAS Rule has forced them to divert resources because they "struggle to prioritize resources given the lack of data on safety." (Pls.' Opp. 16–17; *see also* Compl. ¶¶ 19–28.) Plaintiffs further contend that they suffer concrete and particularized injuries in "paying for access to resources that aid them in researching [the secretly-affirmed GRAS substances]—or pay[ing] consultants to monitor these resources—to unearth the identity of GRAS substances and try to

understand their potential risks." (Pls.' Opp. at 17.) These purported injuries are not sufficiently distinct from the general mission of the organizations at issue. Moreover, to allow standing based on these allegations alone would mean that any entity that spends money on an issue of particular interest to it would have standing, which would in turn contravene the principle that an entity's "mere interest in a problem" cannot support standing. *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972) (internal quotation marks omitted); *see also Citizens for Responsibility & Ethics in Washington v. Trump*, 276 F. Supp. 3d 174, 191 (S.D.N.Y. 2017) ("If [plaintiff's organization] could satisfy the standing requirement on this basis alone, it is difficult to see how any organization that claims it has directed resources to one project rather than another would not automatically have standing to sue."). Accordingly, Plaintiffs have not established an injury-in-fact based on a "diversion of resources" theory.

2. Informational Harm

"[A] plaintiff suffers an 'injury in fact' when the plaintiff fails to obtain information which must be publicly disclosed pursuant to a statute." *FEC v. Akins*, 524 U.S. 11, 21 (1998). An "informational injury" can satisfy the injury-in-fact requirement of standing only in "very specific statutory contexts where a statutory provision has explicitly created a right to information." *Tummino v. Hamburg*, 260 F.R.D. 27, 31 (E.D.N.Y. 2009) (internal quotation marks omitted). To survive a motion to dismiss, a plaintiff must demonstrate an "inability to obtain information . . . that, on [the plaintiff's] view of the law, the statute requires [to be] ma[de] public." *See Akins*, 524 U.S. at 21; *see also McFarlane v. First Unum Life Ins. Co.*, No. 16-CV-7806 (RA), 2017 WL 3495394, at *7–8 (S.D.N.Y. Aug. 15, 2017) (collecting cases). In other words, a plaintiff suffers a sufficiently concrete injury to confer standing when "denied access to information that, in the plaintiff's view, must be disclosed pursuant to a statute and

when there is 'no reason to doubt' that the information would help the plaintiff within the meaning of the statute." *McFarlane*, 2017 WL 3495394, at *7 (quoting *Akins*, 524 U.S. at 21).

Here, Plaintiffs' alleged right to obtain information under the FDCA is too attenuated from the statute from which they seek redress to accord standing. Plaintiffs allege that the GRAS Rule deprives Plaintiffs and their members of information that would otherwise be available to them through the FDCA's food additive petition process. (*See* Compl. ¶¶ 20–28, 33–39, 43, 54–60, 67, 112–119). Between 2003 and 2013, almost all new food chemicals were designated as GRAS rather than going through the food additive petition process, *id.* ¶ 71, even though many of these chemicals are allegedly indistinguishable from food additives, *see id.* ¶¶ 116–17. Because the FDCA guarantees that certain information about food additives must be publicly disclosed, Plaintiffs argue that they are denied information under the GRAS Rule that would otherwise be available to them if these food chemicals were deemed food additives rather than GRAS substances. Plaintiffs' alleged right to obtain information is thus not directly attributable to the language of the GRAS Rule, which I find insufficient to accord Article III standing. Put simply, the FDCA requires information about food additives—not GRAS substances—be made public, and Plaintiffs must show a right to information pertaining to GRAS substances. *See Trummino*, 260 F.R.D. at 31 (concluding Plaintiffs had no standing where FDA was not required to publicly provide information that Plaintiffs desired for their advocacy efforts). Accordingly, Plaintiffs have not established an injury-in-fact based on informational harm.

3. Harm to Members

"To establish injury in fact based on exposure to a potentially harmful product, a plaintiff must show 'a credible threat of harm' due to that exposure." *NRDC v. FDA*, 710 F.3d 71, 81 (2d

Cir. 2013) ("*NRDC*") (quoting *Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003)). "[T]he relevant 'injury' for standing purposes may be exposure to a sufficiently serious risk of medical harm—not the anticipated medical harm itself." *Baur*, 352 F.3d at 641. This analysis is highly case-specific, and "the risk of harm necessary to support standing cannot be defined according to a universal standard." *Id.* at 637. However, "to support standing, the plaintiff's injury must be actual or imminent to ensure that the court avoids deciding a purely hypothetical case in which the projected harm may ultimately fail to occur." *Id.* at 632.

In *Baur*, the plaintiff, a citizen, sought to require the Department of Agriculture to "label all downed cattle as adulterated." *Id.* at 628. Relying on the risks associated with Bovine Spongiform Encephalitis—commonly known as "mad cow disease"—the plaintiff argued that "exposure to downed cattle posed a significant health risk and that the elimination of downed cattle from the food stream was necessary to protect public health." *Id.* Although the disease had not been detected in the United States, the Second Circuit concluded that "an enhanced risk of disease transmission may qualify as injury-in-fact," and that the plaintiff had alleged a credible risk of personal harm based on potential future exposure to contaminated beef. *Id.* at 628, 636. Thus, where a plaintiff alleges exposure to potentially harmful products in the specific context of food and drug safety suits, such injuries are cognizable for standing purposes. *Id.* at 633.

Plaintiffs CFS and EDF have shown a risk of harm consistent with the requirements of *Baur* in alleging that the GRAS Rule poses a credible threat of harm to their members. Specifically, members of CFS and EDF have been and will be exposed to potentially dangerous substances that were introduced into the food supply without FDA oversight, public participation, or the opportunity for judicial review. (Compl. ¶¶ 13, 22, 26, 47, 72, 112, 115.)

Plaintiffs CFS and EDF also explicitly identify multiple substances that manufacturers determined to be GRAS and used in food despite concerns raised by FDA about their safety, as well as additional undisputedly dangerous substances that Plaintiffs reasonably anticipate will be introduced into the food supply under the GRAS Rule. (*Id.* ¶¶ 75–78, 80.) Notwithstanding the Government's arguments to the contrary, these injuries are ongoing and imminent. (*See, e.g.*, *id.* ¶ 115 (alleging that Plaintiffs' members "regularly eat processed foods and are exposed to an increased risk of harm as a result of consuming chemical substances that manufacturers have privately determined to be GRAS without notifying FDA"); *id.* ¶ 22 ("CFS members are being, and will be, adversely affected by potentially unsafe chemical substances added to food"); *id.* ¶ 26 (same with respect to EDF's members).)

The Government argues that Plaintiffs CFS and EDF lack standing based on harm to their members because it is within their members' power to avoid any potential injury from unsafe chemicals added to food. (*See* Gov't Mem. 20.)[4] However, the relevant injury need not be unavoidable in order to give rise to injury for standing purposes. *See NRDC*, 710 F.3d at 80 (stating that "the potential avoidability of . . . exposure" to a potentially harmful substance does not undermine standing); *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 182–83 (2000) (finding that an organization had standing to challenge pollution of a river because its members avoided recreating in the river—without considering whether the members could avoid injury by recreating elsewhere). Moreover, Plaintiffs CFS and EDF contend that their members lack the information and knowledge necessary to protect themselves from the unknown chemical substances added to food. Plaintiffs CFS and EDF point out that, under the

[4] "Gov't Mem." refers to the Government's Memorandum of Law in Support of Defendants' Motion to Dismiss. (Doc. 31.)

GRAS Rule, manufacturers are not required specifically to identify the chemicals they self-qualify as GRAS, nor does the rule require them to disclose information about these substances. Therefore, Defendants' claim that Plaintiffs' members can avoid potential injury lacks merit.

As both parties agree, Plaintiffs CFS and EDF need not identify the names of their injured members at the pleadings stage. *See Bldg. & Const. Trades Council v. Downtown Dev., Inc.*, 448 F.3d 138, 145 (2d Cir. 2006) (finding that plaintiff association bringing suit on behalf of its members need not "'name names' in a complaint in order properly to allege injury in fact to its members"). The remaining Plaintiffs, however, do not allege any credible threat of harm to their members, and as previously discussed, do not meet the requirements of informational or diversion of resources standing. Accordingly, while Plaintiffs CFS and EDF plausibly allege an injury-in-fact based on harm to their members, Plaintiffs Breast Cancer Fund, Center for Science in the Public Interest, and Environmental Working Group have made no showing in support of their Article III standing and must be dismissed from the case.

B. *Traceability*

The traceability requirement of Article III mandates "a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *NRDC*, 710 F.3d at 84 (quoting *Lujan*, 504 U.S. at 560). "To be sure, a plaintiff may not establish injury for standing purposes based on a 'self-inflicted' injury." *Id.* at 85. "An injury is self-inflicted so as to defeat the causation necessary to establish standing, however, 'only if the injury is so completely due to the plaintiff's own fault as to break the causal chain.'" *Id.* (quoting *St. Pierre v. Dyer*, 208 F.3d 394, 402 (2d Cir. 2000)).

With respect to harm to Plaintiffs' members,[5] the Government argues that any compliance failures alleged by Plaintiffs are attributable to a number of factors other than the GRAS Rule, including manufacturers' decisions. (Gov't Mem. 20; Gov't Reply 9.)[6] The Government's argument is overly simplistic. Under the GRAS Rule, a manufacturer is expressly permitted to bypass the food additive process and "self-certify" a substance as GRAS, regardless of the manufacturer's ultimate decision to do so. (*See* Compl. ¶¶ 47, 50–60.) In other words, a manufacturer's decision to use a potentially unsafe substance in food does not negate the fact that FDA's GRAS Rule ultimately allows manufacturers to keep the basis for their determination and the specific substance determined to be GRAS secret from the Government and the public. *See Garelick v. Sullivan*, 987 F.2d 913, 919 (2d Cir. 1993) ("A plaintiff does not lack standing merely because her injury is an indirect product of the defendant's conduct."). Accordingly, Plaintiffs CFS and EDF have made a showing that their claims are traceable to Defendants' actions.

C. *Redressability*

The third requirement to confer Article III standing is that "the injury must be likely to be 'redressed by a favorable decision' of the federal court." *NRDC*, 710 F.3d at 79 (quoting *Lujan*, 504 U.S. at 560–61). To demonstrate redressability, a plaintiff challenging agency action must show only that his injuries might be relieved if the agency were to fulfill its statutory obligations. *NRDC v. Consumer Prod. Safety Comm'n*, No. 16-cv-9401 (PKC), 2017 WL 3738464, at *6 (S.D.N.Y. Aug. 18, 2017) ("*NRDC II*") (quoting *Lujan*, 504 U.S. at 572 n.7); *see also*

[5] Because I find that Plaintiffs fail to allege an injury-in-fact based on harm from diversion of resources or informational harm, I need not and do not address whether Plaintiffs' harm under those theories are traceable to the GRAS Rule and challenged actions.

[6] "Gov't Reply" refers to the Government's Reply Memorandum of Law in Further Support of Defendants' Motion to Dismiss. (Doc. 36.)

Massachusetts v. EPA, 549 U.S. 497, 518 (2007) ("[A] litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant.").

Here, Plaintiffs CFS and EDF meet the minimal burden required at the pleading stage to demonstrate redressability. They allege that a rule consistent with the mandates of the FDCA would, among other things, likely reduce their members' risk of exposure to unsafe chemicals in food. Plaintiffs CFS and EDF need not establish that a lawful rule would entirely prevent any potentially unsafe substance from being added to food. Plaintiffs CFS and EDF allege what is required—that FDA could reduce the rate at which substances that should be treated as food additives are improperly designated as GRAS—and they need not establish that outcome with certainty at this stage. *See NRDC II*, 2017 WL 3738464, at *6 (finding that injuries stemming from exposure to toxic chemicals could be redressed by a final rule limiting use of those chemicals, even though the plaintiff "[could not] establish with certainty that the final rule [would] eliminate exposure"). Based upon the facts alleged in the Complaint, I refuse to give credence to Defendants' arguments that assume a lack of enforcement or incompetence on the part of FDA. Accordingly, Plaintiffs CFS and EDF have adequately alleged at the pleading stage that their claims are redressable.

IV. Conclusion

For the foregoing reasons, the Government's motion is DENIED as to Plaintiffs CFS and EDF because the Court has subject matter jurisdiction over the claims of Plaintiffs CFS and EDF. The Government's motion is GRANTED as to Plaintiffs Breast Cancer Fund, Center for Science in the Public Interest, and Environmental Working Group, and those Plaintiffs are

dismissed from this case.[7]

The parties are instructed to meet and confer regarding the scheduling of discovery and submit a proposed case management plan and scheduling order on or before October 12, 2018. The Clerk of Court is respectfully directed to terminate the pending motion at Document 30.

SO ORDERED.

Dated: September 12, 2018
New York, New York

Vernon S. Broderick
United States District Judge

[7] Plaintiffs Breast Cancer Fund, Center for Science in the Public Interest, and Environmental Working Group's claims are dismissed without prejudice. *See Carter*, 822 F.3d at 54 (noting "that where a complaint is dismissed for lack of Article III standing, the dismissal must be without prejudice, rather than with prejudice").